REMARKS

Claims 1-7 were presented for consideration in the present application. Claims 8-10 were canceled in a prior amendment. The instant amendment adds new claims 11-27. Thus, claims 1-7 and 11-27 are presented for consideration upon entry of the instant amendment.

The specification has been amended to provide a reference to the prior-filed applications that Applicants desire to claim the benefit of and priority to.

The Office Action states that the abstract of the disclosure is objected to because the abstract is too long. The abstract has been amended as suggested by the Examiner. Applicants respectfully request reconsideration and withdrawal of this objection.

Claims 1-7 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner states that the recitation "...and a primary amino group and/or carboxyhydrazine group on a side chain" is indefinite. The claims have been amended to remove the phrase "on a side chain" in order to clarify. Applicants respectfully request reconsideration and withdrawal of this rejection

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2006/0110433 to Terahara (hereinafter "Terahara") in view of WO 00/44846 to Kamiyama (hereinafter "Kamiyama"). Applicants respectfully traverse this rejection.

Independent claims 1 and 5 now provide for a crosslinkable pressure-sensitive adhesive for skin wherein, *inter alia*, a primary amino group and/or carboxyhydrazide group that is present at a density of at least 2 per molecular chain of the copolymer B, a primary amino group and/or carboxyhydrazide group in copolymer B that is included at

a density of one per 5-100 molecular chains of the (meth)acrylic acid ester comonomer, and a crosslinking of copolymer A by copolymer B that occurs as carbonyl groups of the diacetoneacrylamide in copolymer A form covalent bonds by dehydration reaction with the free primary amino groups and/or carboxyhydrazide groups of copolymer B.

Terahara provides for a patch containing a backing layer and adhesive layer, compounded with an adhesive base agent and pergolide and/or a pharmaceutically acceptable salt thereof. In paragraph [0046] of Terahara it states that when the basic nitrogen-including polymer, which corresponds to copolymer B of the present invention, has an amino group, the amino group may be any of either a primary, a secondary and a tertiary group. However, the examples of Terahara in paragraph [0047] only describe tertiary amino group-including amines such as dialkylaminoalkyl(meth)acrylate including dimethylaminoethyl(meth)acrylate and diethylaminoethyl(meth)acrylate.

Furthermore, paragraph [0049] of Terahara describes:

"among the basic nitrogen-including polymers described above, the use of at least one kind selected from methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate is preferable because it enables a higher level of compatibility with respect to the skin permeability of the drug and the patch properties. As methyl methacrylate-butyl methacrylate-dimethyl amino ethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate, commercially available Eudragit E (trade name, manufactured by Rohm) and AEA (trade name, manufactured by SANKYO), respectively, and the like can be used."

Again, the examples of Terahara only use methyl methacrylate-butyl methacrylatedimethylaminoethyl methacrylate terpolymer.

In contrast, the present invention uses an acrylic copolymer (copolymer B) comprising a (meth)acrylic acid alkyl ester as the main constituent component and a primary amino group and/or carboxyhydrazide group. If a tertiary amino group-including amine is used in the present invention, as described in Terahara, the crosslinking reaction between copolymer A and copolymer B does not occur. This is because the crosslinking reaction occurs as carbonyl groups of the

diacetoneacrylamide in copolymer A forms covalent bonds by dehydration reaction with the free primary amino groups and/or carboxyhydrazide groups of copolymer B.

It is clear that the intention of Terahara is to provide adhesives that <u>do not</u> <u>involve crosslinking reactions</u>. For example, in paragraph [0023] Terahara states that "in this connection, the acrylic polymer including no substantial carboxyl group (carboxylic acid group, -COOH) and hydroxyl group (-OH) in the molecule according to the invention means an acrylic polymer that has no carboxyl group or hydroxyl group in the molecule thereof that may become a functional group upon crosslinking".

In addition, Terahara does not specifically describe a (meth)acrylic copolymer comprising a (meth)acrylic acid alkyl ester as the main constituent component and diacetoneacrylamide as the minor constituent component. In contrast, in the present invention it is essential to utilize copolymer A comprising a (meth)acrylic acid alkyl ester as the main constituent component and 3-45wt% diacetoneacrylamide as the minor.

Furthermore, Examples 1-3 of Terahara describe compositions that contain basic nitrogen-including polymer (C) in higher amount than acrylic polymer (A). In contrast, the present invention provides that 100 parts by weight of copolymer A is mixed with 0.1-30 parts by weight of copolymer B. Lastly, it is essential for Terahara to utilize rubber polymer in a large amount while the present invention does not utilize a rubber polymer.

For at least these reasons provided above Terahara fails to disclose or suggest that a crosslinking reaction occurs between carbonyl groups of the diacetoneacrylamide of copolymer A and primary amino group of copolymer B, as provided in independent claims 1 and 5 of the present invention.

Kamiayama provides for an adhesive material that is suitable as a bioadhesive comprising an adhesive polymer and a plasticiser. However, Kamiyama does not provide for a polymer which corresponds to copolymer B of the present invention. In

addition, Kamiyama utilizes low molecular crosslinking agent such as adipic acid dihydrazide while in the present invention crosslinking occurs between copolymer A and copolymer B. Kamiyama fails to disclose or suggest that the crosslinking reaction occurs between carbonyl groups of the diacetoneacrylamide of copolymer A and primary amino group of copolymer B, as provided in claims 1 and 5 of the present invention. Therefore, Kamiyama does not overcome the deficiencies of Terahara.

Furthermore, the drawbacks of Kamiyama are described in paragraph [0006] of the specification of the present invention. Thereafter, Comparative Example 9 describes the invention of Kamiyama which was confirmed to be inferior to the invention of the present application.

Accordingly, Applicants respectfully submit that Terahara and Kamiyama, alone or in combination, fail to disclose or suggest that the crosslinking reaction occurs between carbonyl groups of the diacetoneacrylamide of copolymer A and primary amino group of copolymer B, as provided in independent claims 1 and 5. Therefore, claims 1 and 5, as well as claims 2-4 and 6-7 which depend therefrom, are in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-7.

New claims 11-27 have been added to further point out various aspects of the present invention. It is believed that new claims 11-27 are in condition for allowance.

New independent claims 11 and 13, as well as dependent claims 12, 14-15 and 23-27, provide that copolymer B is a carboxyhydrazide group. Applicants submit that Terahara and Kamiyama do not provide for this carboxyhydrazide group. New claims 16-22 which depend from claims 1 and 5 provide for a crosslinkable pressure-sensitive adhesive for skin which is formed by 100 parts by weight of copolymer A and 0.3-20 parts by weight of copolymer B. Terahara does not utilize nitrogen-including polymer more than 22.2 parts by weight. Accordingly, Applicants respectfully submit that the cited art fails to disclose or suggest the features provided in new claims 11-27.

Serial No. 10/593,242 Art Unit 4161

In view of the foregoing, Applicants respectfully submit that all claims present in this application patentably distinguish over the cited prior art references. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections of the claims. Also, Applicants respectfully request that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

March 30, 2009

Paul D. Greeley V Registration No. 31,019

Attorney for Applicants

Ohlandt, Greeley, Ruggiero & Perle, L.L.P.

One Landmark Square, 10th floor

Stamford, CT 06901-2682

Tel: (203) 327-4500 Fax: (203) 327-6401